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K003440

Summary of Safety and Effectiveness Information	ZAP LASERS, INC.
Premarket Notification, Section 510(k)	DECEMBER 22, 2000

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. *Device Name:*

Trade Name: *SoftLase - Surgical Diode Laser System*
Common Name(s): Surgical Laser System
Classification Name(s): Laser, Surgical

2. *Establishment Name & Registration Number:*

Name: ZAP LASER, INC.
Number: applied/pending

3. *Classification(s):*

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology. (a) Identification. (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide. (2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

(b) Classification. Class II.

Device Class: Class II for all requested indications
Classification Panel: General and Plastic Surgery & Others
Product Code(s): GEX

4. *Section 514 Compliance*

ZAP LASERS, INC. intends to comply fully with the general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

5. *Performance Standards*

United States Food and Drug Administration mandated performance standards for this device exist and are provided under Sections 21 CFR 1010 & 1020. In addition, various voluntary performance standards are utilized. Voluntary standards utilized include Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and cGMP & ISO 9000 series quality regulations.

ZAP LASERS, INC. also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

6. *Special Controls:*

All Class II devices are subject to Special Controls.

7. *Labeling:*

The laser system discussed in this premarket notification will be manufactured by Zap Lasers Inc. and labeled as such. Zap Lasers Inc. will market the system exclusively to healthcare facilities, physicians and dentists. In addition to the usual package and identification labeling, the following additional Warnings, Cautions & Precautions statements are displayed as appropriate on or within the device packaging. They are repeated here for ease of review.

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Warning: Federal (United States) Law restricts this device to sale by or on the order of a physician or dentist only.

8. ***Summary Basis of Equivalence:***

The surgical laser described in this document is substantially equivalent to the referenced legally marketed laser systems in that the operational parameters, indications for use, warnings, cautions and precautions are essentially the same. The only difference in performance characteristics between SoftLase and the Aurora is laser maximum output power. SoftLase has 3.5 watts. The AURORA HL has 1.5 watts and the AURORA SL has 6 watts. The following comparison chart presents the features of all these lasers.

8. ***Predicate Device*** *(legally marketed comparison device)*

Zap Lasers, Inc. believes that the following surgical laser systems are substantially equivalent to the SoftLase - Surgical Laser Diode System.

1. AURORA HL, K992374 and;
2. AURORA SL, K993285

To assist in the overall evaluation of the referenced surgical laser systems, the following Feature Comparison Table presents a brief graphic illustration of the primary features.

FEATURE	*SoftLase - Surgical Diode Laser System*	Aurora HL & SL	SE?
Type of laser	Diode laser	Diode laser	YES
Wavelength	808 ± 5 nm	810nm (+170 nm, -30 nm)	YES
Max output power	3.5 Watt	1.5 Watt (AURORA HL), 6 Watt (AURORA SL)	YES
Operation mode	Continuous wave and pulsed	Continuous wave and pulsed	YES
Delivery system	Multi-mode 400/600 um core quartz fiber	Multi-mode 400/600 um core quartz fiber	YES
Fiber aiming beam	5 mw diode laser, 650 nm	5 mw diode laser, 650nm	YES
Activation means	Foot-switch	Foot-switch	YES
Intended Use and Indications for Use	Excision and Incision Biopsies Hemostatic assistance Treatment of Apthous Ulcers Frenectomy Frenotomy Gingival Incision and Excision Gingivectomy Gingivoplasty Incising and Draining of Abscesses Operculectomy Oral Papillectomy Removal of Fibromas Soft Tissue Crown Lengthening Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) Tissue retraction for Impression Vestibuloplasty.	Same	YES

10. ***Device Description:***

The laser diode assembly with fiber bundle, which contains 3 single diode lasers, each of 1.6 watt output power (Class IV lasers) lasing at about 808 nm. Each diode laser is coupled directly into a 200 um core optical fiber using a special positioner. The assembly also contains a 5-mw power - 650 nm laser diode, which is coupled into the three core fibers. A visible light of this laser is used for aiming the tip of the delivering fiber onto the tissue.

The laser diode power supply, supplies power to the diodes in DC or pulsed mode.

The delivery fiber cables, consist of multi-mode, single core optical fibers available in 400 and 600 um diameters. The standard SMA 905 fiber connector terminates one end of the delivery fiber, which is attached to the SMA union at the rear panel of the laser box. The other end of the fiber is stripped of its protective jacket and is cleaved to provide laser radiation output.

The foot-switch, is a standard (UL-approved) commercial foot-switch/pedal that provides hands-free ON/OFF capabilities. This controls initiation/termination of laser power from the distal end of the delivery fiber. Each ***SoftLase Laser*** is provided with two safety goggles, one fiber stripper and one diamond wedge scribe for fiber cleaving.

11. ***Applicant Name & Address:***

Zap Lasers, Inc.
399 Main Street
Koror, Palau 96940

12. ***Company Contact:***

Mr. Tim Taunton
Zap Lasers, Inc.
399 Main Street
Koror, Palau 96940
680.488.1859 - 680.488.1858 - fax

13. ***Submission Correspondent:***

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C -100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

14. ***Manufacturing Facility:***

The devices are physically manufactured in the Republic of Palau by Zap Lasers Inc. and imported into the United States. The devices are manufactured by Zap Lasers Inc. for distribution in the U.S.A.

15. ***Sterilization, Packaging & Storage Information:***

The diode laser device is not supplied sterile. Packaging materials are typical medical grade tubes, plastic trays, peel-type pouches of the generic mylar/non-woven sandwich variety, etc. All packages should be intact upon receipt. Packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. If the package or product is damaged, the product should not be used and should be returned. Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following cleaning, sterilization and accepted surgical sterile technique.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2001

Zap Lasers, Inc.
c/o Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523

Re: K003440
Trade/Device Name: SoftLase and CureLase Surgical Diode Laser
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: December 22, 2000
Received: February 21, 2001

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: **K003440**

Device Name(s): ***SoftLase & CureLase - Surgical Diode Laser System***

Intended Use(s) of the Device:

The ***SoftLase - Surgical Diode Laser System*** is to provide the ability to perform intraoral soft tissue dental, general, oral maxillo-facial and cosmetic surgery. The SoftLase is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber optic delivery system.

The device will be used in the following areas: general and cosmetic dentistry otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery. The following are the oral-pharngeal indications for use for which the device will be marketed:

- Excision and Incision Biopsies
- Hemostatic assistance
- Treatment of Apthous Ulcers
- Frenectomy
- Frenotomy
- Gingival Incision and Excision
- Gingivectomy
- Gingivoplasty
- Incising and Draining of Abscesses
- Operculectomy
- Oral Papillectomy
- Removal of Fibromas
- Soft Tissue Crown Lengthening
- Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- Tissue retraction for Impression
- Vestibuloplasty.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003440

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)